

Date: 2/29/2004

To: Commissioner John Stephen, Health and Human Services and  
William Kassler, MD, Medical Director

From: Frank LlikOS1uS R. Ph. and Merton Dyer R. Ph.

Subject: Report on visit to CanadaDrugs.com in Winnipeg, Canada, Manitoba

At the request of Commissioner John Stephen, DHHS, and William Kassler, MD, Medical Director, pharmacists Merton Dyer of Peterborough and Frank Lukosius of Bedford traveled to Winnipeg, Canada in the province of Manitoba on February 25th, 2004. Mr. Dyer is a former NH State Legislator, former independent pharmacy owner and NH Department of Corrections employee. Mr. Lukosius, a chain drug store employee, also owned several independent pharmacies, a home infusion pharmacy and was a consultant to Community Health Services Pharmacy Program in Derry.

The purpose of the trip was to "inspect" and "evaluate" CanadaDrugs.com, a Canadian mail-order pharmacy, identified by DHHS to be accredited by the Internet and Mail order Pharmacy Accreditation Commission (IMPAC). CD.com is the first Canadian mail-order pharmacy to complete IMPAC's quality and standards accreditation.

IMPAC is an American association developed in response to concerns expressed by consumers and the government. Accreditation means the pharmacy is in full compliance with core standards and required quality elements. These include quality assurance, pharmacy management, confidentiality, consumer safety, customer satisfaction, health information technology, website content, shipping and handling and customer call center functions.

We had about 6 hours to evaluate the facility. We felt the staff was very open and forthcoming and we covered a great deal of information in that period of time.

We began with a conference with the President, the Pharmacist owner / CEO, and the Pharmacy Manager. We spent several hours discussing all aspects of the business. The organizational structure of the company includes a Director of Pharmacy, Marketing Analyst, Quality Assurance Manager, in-house Industrial Engineer, Process Engineers, HR, IT, in house Legal Counsel and more. The company is a process driven company. They appear extremely efficient. They are very concerned with safety, accountability, quality and service. The company is independently owned by a pharmacist, who also owns 4 small Clinic pharmacies in Manitoba. The company began in April, 2001 in a 500 sf office and

has grown to 24,000 sf with 220 employees. The new 9000 sf expansion area was being fitted with conveyor belts and shelving while we were there.

The company has no legal problems with the Province Pharmacy Regulators or any pending legal action against them. There have been at least 6 inspections from local regulators not including visits from various US State inspection teams. The Province Pharmacy Regulators inspections are very similar in nature to US pharmacy inspections. No other lawsuits are pending.

The company has no malpractice insurance and has been unable to obtain any from anywhere in Canada primarily because of the new concept and rapid growth of the Canadian mail order business. Staff pharmacists have their own individual malpractice insurance. Several pharmacists including the owner are also licensed pharmacists in various US states such as North Dakota and Michigan. The facility and the pharmacists are licensed as required by the Province of Manitoba.

Pharmacy techs are not required to have licenses, however, all techs are hired from a University training program. All customer call center reps must complete an in house 2 week training program before they are allowed to accept calls. The ratio of pharmacists to techs is regulated at 1: 1 + 1 which means 1 pharmacist may supervise 2 techs or 5 pharmacists may supervise 6 techs. This ratio is much more stringent than most US pharmacies. During the visit, every employee was seen to have an electronic ID badge which was necessary to enter and leave secure areas throughout the facility.

The order process and filling process were observed from start to finish. The call center is now set up in 2 groups, one being a new patient center, the other a customer service center, each with separate functions. This is being changed to one call center group covering all aspects of service. Phone calls are expected to be answered in 20 seconds. A pharmacist is assigned to take calls when requested by patients or practitioners. Hours are 7:30 AM to 11 PM Central Time. Hours are expected to be expanded soon. When a call is received into the call center inquiring about placing a new order, a packet is mailed to the patient explaining what is necessary to obtain a prescription medication. Fax or e- mail may also be used if available.

A patient must mail in an original prescription from their practitioner for a 90 day supply of medication. The patient must complete a Patient Form which requires a medication history, allergies, a medical history, an offer of counseling by phone by a pharmacist, a disclaimer stating that any and all claims against the company would be filed in the Province of Manitoba and that the patient meds would become the property of the patient as soon as the meds leave the facility. This addresses the import / export legalities. The company now accepts a fax copy of a prescription and will mail the initial order but not the re-order until the original is received. That process will be changed soon to allow for mailing the order only when the original

is received. Faxing an Rx from a patient to a pharmacy is not allowed in NH. When the Rx is received, it is matched with the patient medical and drug information by a tech, then screened by a pharmacist for clarity. Phone calls to practitioners may be made by the pharmacist at this time. Offers of generic or therapeutic equivalents may be made and substituted with the authority of the practitioner (PCP) and the patient per the order form selection. Some of these generics are not approved for sale in the US, due primarily to patent rights on the Brand name drugs. The first pharmacist forwards the information and the prescription written by the American practitioner to a Canadian Physician to verify the therapy, and histories and co-sign the prescription. The company has 6 physicians reviewing their records, all from out of Manitoba. Manitoba Medical authorities were contemplating some type of reprimands for any physicians involved in reviewing mail order pharmacy records and co signing prescriptions. This is not the case in some other provinces. When the Canadian Physician completes the review and authorization, the Rx data is entered into the computer by a tech. The label generated and the patient file are assembled for a technician pre check assuring that all the appropriate information and authorizations are available for review. A therapeutic screening is then performed by a pharmacist. Any calls to the patient or practitioner may also be made by this pharmacist. The order is then picked by a technician, placed in a "pizza box" with the original Rx and a final check is performed by a pharmacist. This entire process is much more stringent than most US pharmacies and provides the patient with assurance that their order has been filled correctly. Billing, packaging and shipping then occur. Canadian Postal picks up orders 3 times per day and delivery time is estimated at less than 14 days, on average about 9 days to the US. Controlled drugs are not available. Only 3 refrigerated items are mailed, Insulin, Xalatan, and Miacalcin and stability studies are documented for these products. Child resistant containers are used unless otherwise requested. Caps on stock bottles without CRC are changed to CRC caps. All Rx's are dispensed in original containers when possible. Much of the packaging in Canada is designed as unit of use, in 30s or 90s. This keeps counting at a minimum.

Complaints are very rare, primarily concerning delivery problems. The comments of the staff reflected a feeling of satisfaction by the vast majority of patients that they could afford significant savings on their necessary medications.

The return policy is very liberal. Any med, for whatever reason, may be returned within 30 days for a full refund. Return shipping will also be included. Opened bottles are destroyed and unopened bottles are placed back in stock.

Drug information sheets are included with all medication orders and the offer to counsel is offered to each patient on the initial Patient Form. A pharmacist is always available by toll free phone for any questions.

Drug recalls in Canada are similar to the US and the company has a process for notifying patients of recalls. There has not been an equivalent to a Class I recall (US), where the patient has to be called immediately, in Canada for at least 12 years.

Medication supply shortages continue to be a problem. Some US drug companies such as Pfizer, Glaxo, and Lilly are limiting quantities of medications to Canadian wholesalers. These companies are requesting information on quantities of drugs being ordered by Canadian pharmacies.

Stock bottles of many Canadian Brand name products are manufactured by the same Brand name American companies. The packaging and the product may look different due to labeling requirements and the manufacturing process. All products are approved by HPFB the equivalent to the US FDA. It would be difficult to believe that HPFB would be any less stringent in their enforcement of the regulations which provide Canadians with safe, pure, stable, effective medications than the US FDA regulatory process.

The generics that we checked were primarily from 4 companies, 2 of which we use frequently in the US, 1 other is a subsidiary of Merck, and the other was founded by a Swiss firm (Rhone Poulanc) with offices in the US, and is now owned by a German generic manufacturer. They include Novopharm, Apotex, Genpharm, and Rhoxalpharm. Of the top 10 generics available, only 5 are approved for sale in the US, however, the Canadian generic used is manufactured by a major generic entity. Many Brand and generic companies in the US do not manufacture their products in the US. Drugs distributed by major US companies or affiliates are often **manufactured in Ireland, Israel, Canada, Slovenia, Sri Lanka and more.**

Based on what we saw, we feel that CanadaDrugs.com offers a safe, cost effective, confidential, alternative for those wishing to purchase drugs through Canadian mail order. 75% of the patients using this service are over 60 years of age. The assurance that quality brands and generics are being used, many by the same manufacturer shipping meds to the US, gives us confidence that safe medication practices are being observed. The accuracy of the 3 pharmacist review and 1 physician review far surpasses anything that we have seen in US pharmacies. It has been stated that the process of having a Canadian physician co-sign and review a patient file is not good medical practice. We must remember that the patient still has a Primary Care Physician managing their care. No medication is changed, added or deleted without the PCPs, authority. US patients are charged more than Canadian citizens for the same medications.

Canadian pharmacists receive a small mark up over cost and a dispensing fee of up to \$8 for each and every prescription they fill. Wholesale prices are determined by the government and all pharmacies pay the same price. It levels the playing field for competition. The wholesalers are regulated by the Province and follow the strict regulations on buying or transferring medication from pharmacy to pharmacy or wholesaler to pharmacy. It is unfortunate that the US drug companies have chosen to charge such high prices. It is unfortunate that local pharmacies and pharmacists have been viewed as the "bad guys". There is no profit in US retail pharmacy today. The result is that when people have to choose between food and their medication, they must bypass an important healthcare resource in their community pharmacist. Until the drug company prices are regulated or a formulary system is initiated, the US consumer, with no insurance coverage, has no alternative but to seek other sources to purchase cost effective, safe medications.

There was some discussion that the State of NH was considering using Canadian meds for the Correctional system and possibly the Medicaid program. CanadaDrug.com will only provide meds to patients for "own use" in a 90 day supply maximum in original stock bottles. They cannot and will not ship bulk medications for reuse or resale.

We feel that CanadaDrugs.com provides a high quality of service, excellent clinical oversight, and a modern efficient operational processes.

We did not have the opportunity to visit any other pharmacies, however, we would have no problem recommending CanadaDrugs.com to be the web site of choice for NH residents.

Respectfully submitted,

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